

MAR 12 2004

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510(k) SUMMARY

510(k) NUMBER: ~~PENDING~~ K040295

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8327
FAX (949) 713-8205

CONTACT PERSON: Cheryl Blake
Director of Regulatory Affairs and Clinical
Programs

DATE OF PREPARATION: January 15, 2004

NAME OF DEVICE: Laparoscopic Monopolar Scissors

CLASSIFICATION NAME: Gynecologic laparoscope and accessories
(Regulation Number 21CFR 884.1720 and
accessories).

TRADE NAME: Applied Laparoscopic Monopolar Scissors

PREDICATE DEVICE: United States Surgical Auto Suture® Endoscopic
Scissors, which is cleared to market under
premarket notification K903206

INDICATIONS FOR USE: The Applied Laparoscopic Monopolar Scissors is indicated for use in gynecologic and general endoscopic procedures for mobilization and transection of tissues. The device with a 5mm diameter insulated shaft has a male cautery connection on top of the handle and may be used for monopolar cautery when attached to standard cautery cables and their generators.

INTENDED USE: The Laparoscopic Monopolar Scissors is intended for use in general or gynecological surgical procedures that utilize minimally invasive surgical procedures. The primary function of the device is to provide the surgeon the ability to manipulate tissue during minimally invasive surgery.

SUMMARY STATEMENT:

The Applied Laparoscopic Monopolar Scissors is designed to for a variety of general, gynecologic and urologic endoscopic procedures for mobilization and transection of

tissue. The Applied Laparoscopic Monopolar Scissors consists of a reusable handle and disposable insulated shaft with scissor blades. The device has a 5mm diameter disposable insulated shaft that connects to a reusable Polyarylsulfone/stainless steel handle with a male cautery connector to be utilized for monopolar cautery when attached to standard monopolar cautery cables and their generators.

The disposable shaft consists of a stainless steel outer shaft housing an actuation rod, which connects to the scissor blades and handle actuation rod. The disposable shaft is to be supplied sterile in single unit pouches. The scissor blade length is 17.4mm and the blade opening is 5.59mm and will be available in working lengths of 32cm, 38cm, and 45cm.

The reusable handle is comprised of Polyarylsulfone male and female handles with various stainless connectors and contacts. The reusable handle will be supplied non-sterile. The handle includes a 360° rotation knob for user convenience.

The reusable handle is steam sterilized by the user and then connected to the sterile disposable shaft. Following use the shaft and handle are disassembled. The shaft is disposed of and the handle is cleaned and re-sterilized.

The device is in compliance with ISO 10993 for Biocompatibility. The Applied Laparoscopic Monopolar Scissors Shaft is sterilized using 100% Ethylene Oxide (EO). Applied's 100% EO sterilization cycle provides a sterility assurance level of 10^{-6} . Sterilization validation for Applied Medical's EO cycle uses three half-cycle validation runs, which incorporate biological indicators and temperature monitors distributed throughout the load to verify gas penetration and profile temperature distribution. Spore strip biological indicators (BIs) of *Bacillus atrophaeus* var. *niger* (formerly known as *Bacillus subtilis*) with a population of 10^6 are used to monitor routine finished product sterilization loads. Sterilant residue levels will be in compliance with ANSI/AAMI/ISO 10993-7:1995 for limited exposure devices which is 20 mg ethylene oxide and 12 mg ethylene chlorohydrin.

The Laparoscopic Monopolar Scissors Handle is provided non-sterile. Sterilization instructions are provided in the Product Information Data Sheet. The Applied steam sterilization and cleaning validation methods are based on the AAMI TIR No. 12 – 1994, Designing, Testing and Labeling Reusable Devices for Reprocessing in Health Care Facilities: A Guide for Device manufacturers, and proves a sterility assurance level of 10^{-6} . Sterilization validation of the steam sterilizations is based on three sterilization cycles at one-half the exposure time. The use of *Bacillus stearothermophilus* spore strips or inoculum is the utilized indicator.

The Laparoscopic Monopolar Scissors is substantially equivalent to the United States Surgical Auto Suture® Endoscopic Scissors, which is cleared to market

under premarket notification K903206, in intended use, design, and use methodology and is manufactured from similar materials.

Applied Medical is the manufacturer of the device and has followed design control regulations per 21 CFR § 820.30. The design controls have been in place since 1997 and have been audited by FDA on several occasions. The design of the Laparoscopic Monopolar Scissors was within the Applied Medical Design Control System.

A Design Risk Assessment Profile was conducted in accordance to Applied Medical internal Standard Operating Procedures, EN 1441 standards, ISO 9001/ISO 13485, AAMI/ISO TIR 14971, and 21 CFR § 820.30, validation and verification activities addressed the profile. Based on the risk analysis, validation and verification activities were formally controlled and addressed by Applied Medical, the activities included the methods, tests used, and acceptance criteria applied.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2004

Applied Medical Resources Co.
% Ms. Elizabeth Drew
Underwriters Laboratories, Inc.
Santa Clara Division
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K040295
Trade/Device Name: AMRC's Laparoscopic
Monopolar Scissors
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope
and accessories
Regulatory Class: II
Product Code: 85 HET
Dated: February 23, 2004
Received: February 26, 2004

Dear Ms. Drew:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

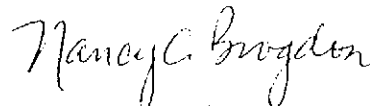
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure


INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Applied Laparoscopic Monopolar Scissors "Indications for Use" as required.

510(k) Number: ~~Not assigned~~ K04 0295

Device Name: Applied Laparoscopic Monopolar Scissors

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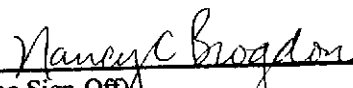
Signature:  Title: Director RA/Clinical Programs Date: 1/15/04

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
 (Per 21 CFR 801.109)

OR Over-The -Counter Use ☐


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

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